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K012466

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Section 2 Summary and Certification

510(k) Summary of Safety and Effectiveness

Date:

July 31, 2001

Submitter:

GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person:

Karen Webb
Sr. Regulatory Affairs Specialist
GE Medical Systems Information Technologies
Phone: (414) 362-3329
Fax: (414) 918-8114

Device: Trade Name:

BIS/EEG Module

Common/Usual Name:

Electroencephalograph (EEG)

Classification Names:

21 CFR 882.1400 Electroencephalograph

Predicate Devices:

K974496, K923043 & K011843 Aspect Medical Systems, Inc. EEG
Monitor with BIS Engine

Device Description:

The BIS/EEG Module is part of a modular system used to monitor the state of the brain by data acquisition of EEG signals. The module is also used as an aid in monitoring the effects of certain anesthetic agents using Aspect's Bispectral Index® parameter.

BIS/EEG Module works as a component of a GE Medical Systems Information Technologies host monitoring system and does not function on its own. The BIS/EEG Module provides information obtained from the sensors/electrodes to the bedside monitor for display.

Intended Use:

The BIS/EEG Module is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The BIS/EEG Module is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The BIS/EEG Module is intended to monitor the Bispectral Index (BIS), a processed EEG variable which may be used as an aid in monitoring the effects of certain anesthetic agents.

Technology:

The BIS/EEG Module employs the same functional scientific technology as its predicate device.

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Test Summary:

The BIS/EEG Module and its host patient monitoring system comply with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the BIS/EEG Module:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing
- Environmental testing

Conclusion:

The results of these measurements demonstrated that the BIS/EEG Module is as safe, as effective, and perform as well as the predicate device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Ms. Karen Webb
Senior Regulatory Affairs Specialist
GE medical Systems
Information Technologies
8200 West Tower Avenue
Milwaukee, Wisconsin 53223

APR - 9 2012

Re: K012466
Trade/Device Name: BIS/EEG Module
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLW, OLT, ORT, OMC
Dated (Date on orig SE ltr): July 31, 2001
Received (Date on orig SE ltr): August 1, 2001

Dear Ms. Webb:

This letter corrects our substantially equivalent letter of October 1, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

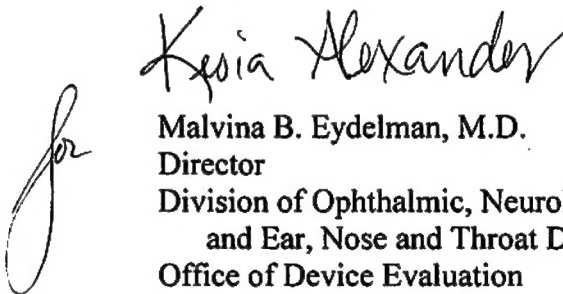
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Malvina B. Eydelman". The signature is fluid and cursive, with the first name being the most prominent.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K012466; 510(k) filed on July 31, 2001

Device Name: BIS/EEG Module

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

for Mark N. Melkus
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K 012466